

EXHIBIT 17

PARK JENSEN BENNETT LLP

To: Michael D. Reisman, Esq.
Assistant Attorney General, Health Care Bureau
Office of the Attorney General of the State of New York

Maria A. Barton, Esq.
Vice President, Deputy General Counsel
Purdue Pharma L.P.

From: Douglas R. Jensen
Tami Stark

Subject: Auditor's First Report on Purdue Pharma's ADD Program

Date: October 7, 2016

In May 2016, Purdue Pharma L.P. ("Purdue") selected, and the Office of the Attorney General of the State of New York ("OAG") approved, Douglas R. Jensen as Auditor under the Assurance of Discontinuance agreement executed on August 19, 2015 (the "AOD"). This constitutes the first report of the Auditor pursuant to paragraph 41.c. of the AOD. The Report is divided into five parts: (I) summary of findings; (II) description of the scope of the Auditor's activities to date; (III) the Auditor's findings with respect to Purdue's compliance with Section IV.A. of the AOD and the reasonableness of its determinations whether to continue marketing opioid products to particular health care providers ("HCPs"); (IV) the Auditor's evaluation of additional questions raised by the OAG; and (V) anticipated next steps and process improvements.

I. Summary of Findings

The Auditor's work has focused principally on two broad questions: first, whether Purdue is managing its ADD Program in compliance with Section IV.A. of the AOD; and second, whether Purdue's determinations regarding whether to continue marketing to HCPs subject to ADD Reports were reasonable.

As to the first question, the Auditor concludes that Purdue is operating the ADD Program in compliance with Section IV.A. Set forth below (see Section III.A.2.) is a paragraph-by-paragraph description of the requirements posed by Section IV.A. and the evidence indicating the Company's compliance with those requirements. On a more general level, the evidence reviewed by the Auditor and the Auditor's interactions with its Law Department indicate that the Company is approaching the ADD Program conscientiously and in good faith. While glitches have occurred (see for example discussion below at 41) in the Auditor's view such issues do not result from a lack of commitment to the Program.

As to the second question, the Auditor concludes that the Company's determinations whether to continue marketing were reasonable. For context, during the period of review a total of 98 ADD Reports were submitted, and of these 98 Reports the Law Department initially determined to cease calling 73 of the HCPs (this number included 34 "automatic" placements on the No-Call List¹), and to continue calling 25 of the HCPs. The Auditor focused most of its attention on those HCPs placed in the continue calling category, and found the Law Department's determinations reasonable.

¹ Automatic determinations occur if a news story indicates an adverse criminal or licensing action taken against an HCP and the sales force has not called on the doctor during the prior year.

In so doing, it is important to note that the Auditor's evaluations, as well as the Company's determinations, constitute judgment calls that took many different forms. In many instances, the Auditor immediately agreed with the Law Department's determination with little need for follow-up. In some instances, the Auditor raised questions about the Law Department's initial determination, as a result of which the Law Department gave further consideration to the HCP and as a result either placed the HCP on the No-Call List or under review. And finally, in some instances the Auditor found the Law Department's determination reasonable, but because the determination was a closer call and raised issues of possibly broader application, the Auditor has chosen to bring them to the Attorney General's attention as a separate category (see discussion below at Section III.B.4.). In all cases, however, based on our interactions with the Law Department, it has approached these determinations diligently and in good faith.

Of note, none of the determinations reviewed by the Auditor arose from ADD Reports filed in the State of New York. As the OAG is aware, during the period under review no ADD Reports were filed in New York based on field observations made by the sales force (although over 20 New York HCPs were placed on the No-Call List as a result of media reports of criminal charges or license revocations). Accordingly, at least for this review period the Auditor is not in a position to evaluate the Company's determinations with respect to such Reports.

This fact led the OAG to request that the Auditor address an additional question: whether it could offer any explanation for the absence of sales force reports in New York during the review period. As discussed below, the Auditor can offer speculation as to that subject, but no definitive answer. Nevertheless, the Auditor can confirm that numerous ADD Reports have been filed by the sales force in other parts of the country, and has seen no evidence that Purdue is

treating the State of New York any differently in this respect. Thus, it may be that the lack of sales force reports in New York for this review period is an anomaly, but in any event the Auditor will continue to monitor this in the next review period.

II. Scope of Activities

The Auditor's Role is defined by Paragraph 41.b. of the AOD, which states as follows:

Purdue shall provide the Auditor with information about its implementation of the ADD Program along with ADD Reports filed during the year and the Company's determination regarding each report. The Auditor shall evaluate Purdue's compliance with Section IV.A. . . . and the reasonableness of Purdue's decisions regarding whether to continue marketing or promoting opioid products to the [Health Care Professional] at issue in each ADD Report. The Auditor shall present its findings in a written report (the "Auditor's Report") to the OAG and Purdue. The first Auditor's Report shall be due one (1) year after the Effective Date.

Although the first anniversary of the Effective Date was August 29, 2016, the parties agreed to extend the deadline for the first Auditor's Report to October 7, 2016.

The Auditor was appointed in May 2016, and began its work at that time. During the course of its investigation, the Auditor received extensive documentation from the Company, including: Purdue's Abuse & Diversion Detection Standard Operating Procedure 1.7.1; Purdue's monthly updates to the OAG; Purdue's Sales Training Presentation and Quiz for the ADD Program; Purdue's Ethics & Compliance Call Note Review-Working Practice Document; the Law Department- Working Practice Document; data on New York ADD reports and HCPs who were added to the No Call list; Incentive Compensation Guides for 2016; information about the I-STOP/PMP- Internet System for Tracking Over-Prescribing- Prescription Monitoring Program; screen shots from the Phoenix Territory Management system; examples of No-Call emails; a

spreadsheet of, and actual emails regarding, “No-Call” notifications when a call is made on a “No-Call” HCP; and emails from the Ethics and Compliance Department regarding Call Notes that contained ADD concerns but there was no ADD Report filed.

The Auditor also had extensive interactions with the lawyers at Purdue having primary responsibility for the ADD Program: Maria A. Barton, Vice President, Deputy General Counsel; Andrea B. Neuman, Associate General Counsel; and Julie Day Marion, Senior Attorney. The Auditor initially met with those lawyers in late May 2016, and in the following four months had numerous conference calls with one or more of them to discuss issues raised by the Auditor’s review of the documents. In addition, Purdue arranged a conference call with [REDACTED] an information technology specialist at Purdue who demonstrated via a WebEx teleconference how the Phoenix system (see description below at Section III.A.1.) works.

A principle focus of the Auditor’s efforts, of course, was to evaluate the reasonableness of Purdue’s decisions whether to continue promoting opioid products to the HCPs at issue in each ADD Report. With respect to that effort, Purdue provided the Auditor with all ADD Reports filed and closed between January 1, 2016 and June 22, 2016² (the “Auditor Review Period”). During the Auditor Review Period, 98 ADD Reports were submitted to the Law Department. In addition, although not required to do so by the AOD, the Company provided us with requests to resume calling (“Requests to Resume Calling”) as to HCPs who had gone onto the No-Call List as a result of ADD Reports filed in earlier years. As we understand it, the AOD did not require the Company to provide those Requests, since Paragraph 41 of the AOD only

² Because Paragraph 40 of the AOD gave Purdue 90 days to certify compliance, and the AOD was executed on or about August 19, 2016, it provided the Auditor with ADD Reports beginning January 1, 2016.

requires the Company to provide the Auditor with ADD Reports filed during the review period, and in these instances the ADD Reports were filed in earlier periods. Nevertheless, there were 15 such Requests during the Review Period, and the Company provided us with copies.

In reviewing the ADD Reports and Requests to Resume Calling, the Auditor determined to focus its efforts on those instances in which the Law Department made a determination to continue calling on the HCP. Accordingly, Purdue provided the Auditor with electronic folders for each of those HCPs. The folders typically contain for each HCP: the ADD Report or Request to Resume Calling; a DEA license screenshot; a state medical board license screenshot; opioid prescription statistics; and Call Notes written by the sales representatives after any visits to the HCP. In addition, some folders contain copies of news articles or state medical board licensing documents concerning the HCP.

In addition to the above documents, a critical component of the Law Department's determinations with respect to the ADD Reports was the information it obtained through its discussions with sales representatives. This information was apparently reflected in the written memos prepared by the Law Department to reflect their determinations. Because those memos were privileged, however, the Law Department did not share them with us. Instead, the Law Department initially sought to provide us with the factual information in lengthy teleconferences during which they described the facts gathered during their investigation. These teleconferences were both unwieldy and an imperfect method of obtaining relevant information, and accordingly the Auditor discussed with Purdue and its outside counsel alternate methods of obtaining the factual information at issue. Ultimately, the Company agreed to provide factual summaries reflecting the facts obtained by the Law Department in the course of its investigations. These

factual summaries describe the source of the report, summarize the Law Department's conversations with the sales representatives and the status of the HCP's medical licenses, prescription history and other relevant facts.

III. Findings

A. Purdue's Maintenance of the ADD Program

To evaluate the Company's compliance with Section IV.A., the Auditor considered each individual paragraph of that Section separately. Set forth below is a paragraph-by-paragraph discussion of the requirements of Section IV.A. of the AOD and the evidence addressing Purdue's compliance with the paragraph. Before turning to that discussion, though, to provide background and context we set forth a general description of the ADD Program and how it functions.

1. General Description of the ADD Program

The basic contours of the ADD Program are described in the Standard Operating Procedures Document that Purdue issued in September 2015 following its entry into the AOD (the "ADD Procedure"). As set forth therein, the ADD Program's objective is to "preclude promotion of Purdue's opioid products in circumstances where there is a concern about potential abuse or diversion related to a particular Prescriber, Pharmacist, his/her patients, or opioid products." Thus, it is designed "to ensure that interactions with Prescribers or Pharmacists that reveal observations or circumstances that suggest potential concerns generate appropriate review and follow up."

The ADD Program applies to "all members of Purdue's field sales organization, medical science liaisons and other Purdue employees and contract or third party sales representatives"

(defined as “ADD Covered Persons” in the Procedure, but for ease of reference we also refer to them in this Report as sales representatives). It provides a detailed list of situations that may suggest an HCP is involved in the abuse or diversion of opioids, and requires the ADD Covered Person to make a prompt report (the “ADD Report”) to the extent she becomes aware of any such situation.

Once an ADD Report is filed, the Law Department is required to evaluate the Report and make a determination whether the Company may continue to call on the HCP. In making that evaluation, the Law Department is guided by a Working Practice Document (the “Law Department Procedure”) issued on or about February 5, 2016. That Procedure governs multiple facets of the Law Department’s role in the ADD Program, including its evaluation of ADD Reports. Pursuant to that Procedure, the Law Department is required to consider a number of factors, including discussions with field personnel concerning their observations of the HCP, recent prescribing history, the status of the HCP’s medical license and DEA registration, Call Notes reflecting any sales representatives’ interactions with the HCP, and any relevant publicly available information.

Pending the Law Department’s review of an ADD Report, and unless and until a determination to continue calling is made, the HCP remains on the “No-Call List,” and the ADD Procedure prohibits any sales calls on the HCP. To ensure that sales representatives have notice of an HCP’s status on the No-Call List, the Company principally relies upon its Phoenix system. That system is a central database and communications network used as a general purpose tool for managing the day-to-day activities of sales representatives (not just for the ADD Program). For example, to schedule a sales call on any HCP (not just those named in an ADD Report), sales

representatives are expected to do so through the Phoenix system, among other reasons to ensure coordination of sales force efforts. Similarly, when making a report on a sales call (and such reports are required), sales representatives are expected to do so through Phoenix, among other reasons to ensure that the Company has a centralized record of such calls. Thus, sales representatives are required to manage their day-to-day sales activities through Phoenix and, as a practical matter, we are informed that they access it multiple times in any typical business day.

It is through the Phoenix system that the Company provides alerts about an HCP's presence on the No-Call List. The Phoenix system provides such alerts in multiple ways, including the following. First, by 6:00 a.m. on the day after a No-Call determination has been made, the Phoenix system generates a notification email to every sales representative covering the sales territory in which the HCP is located. Second, when a sales representative first logs in to the Phoenix system, the home page features an alert section in bold red font that includes the names of any HCPs added to the No-Call List in the sales representative's territory in the previous 15 days. Third, when a sales representative accesses the page for a particular HCP or attempts to schedule a call on that HCP, the system generates an alert in bold red font that the HCP is on the No Call list.

If, notwithstanding such alerts, a sales representative were to have contact with an HCP on the No-Call List and enter such contact in the Call Notes, the Phoenix system also generates a notification of that fact to the Law Department. In such instance, the Law Department conducts an investigation to determine the reason for the contact³ and pursue appropriate follow-up.

³ The reasons for such contact vary. In some instances, based on records provided to us by the Company, a sales representative would inadvertently encounter a No-Call HCP during the

2. Paragraph-by-Paragraph Description

In addition to the above general description, the following will provide a paragraph-by-paragraph discussion of the requirements of Section IV.A. of the AOD and the evidence addressing Purdue's compliance with each paragraph.

Paragraph 28 of section IV.A. requires that "Purdue shall continue to maintain its ADD Program . . ." as well as "implement the modifications set forth" in subsequent paragraphs of the AOD. As made clear by the above general description, Purdue is continuing to maintain the ADD Program. With respect to the modifications of the Program required by the AOD, those modifications are discussed below.

Paragraph 29 of Section IV.A. requires that ADD reports be filed when ADD Covered Persons observe or learn of situations that may suggest that an HCP may be involved in the abuse or diversion of opioids. In addition to the situations previously identified as triggering a report (described in Paragraph 10), the AOD requires Purdue to add two additional items to the list of triggers: (a) where an HCP "lacks understanding of the risks associated with prescribing opioids," for example by stating that he or she lacks information about the risks of addiction; and (2) facts suggesting that an HCP's patients are seeking opioids for misuse, including for example an HCP who has failed to comply with NY's I-STOP Program.

course of a visit to another (unrestricted) HCP practicing in the same medical office, and consistent with ADD Procedure would note the encounter in her Call Notes after the fact. In other instances, the Law Department has directed a sales representative to visit a No-Call HCP's office as part of its investigation. In other cases, a sales representative may have scheduled a call on an HCP before the Phoenix system reflected that the HCP had been placed on the No-Call List. During the period of January 1, 2016 through September 15, 2016, the Law Department received notifications of 24 such instances. Pursuant to our request, the Law Department provided a spreadsheet and back-up documentation reflecting the reasons for these notifications and their disposition by the Law Department.

Consistent with this requirement, the Auditor has confirmed that Purdue amended its ADD Procedure to include the above two factors. Prior to that amendment, the Procedure listed 13 situations that would trigger an ADD report. On or about September 2015, Purdue updated the Procedure to include two additional triggers, which required the filing of ADD Reports where:

14. A Prescriber lacks understanding about the risks associated with prescribing opioids. For example, a Prescriber who states that he or she does not have basic information about the risk of addiction associated with opioid therapy.

15. Facts that suggest that the Prescriber's patients are seeking opioids for misuse and abuse, including but not limited to facts that suggest that a Prescriber has failed to comply with his or her state's prescription monitoring program. For example, failure to comply with New York's Internet System for Tracking Over Prescribing/Prescription Monitoring Program (I-STOP/PMP).

In addition to updating the procedure, the Auditor's review of ADD Reports confirms that Purdue employees have filed reports where at least the first trigger was present. For example, in April 2016, a sales representative in Pennsylvania submitted an ADD Report stating that Dr. Ellis "lacks understanding about the risks associated with prescribing opioids."

Paragraph 30.a. of Section IV.A. contains two components. First, it requires that Purdue continue to conduct inquiries upon identification of potential abuse, diversion or prescribing of opioids, and that such inquires must include "review of the HCP's prescribing history and relevant facts about the HCP's practice." Second, it requires that Purdue "take such further steps as may be appropriate" as a result of such inquires, which shall include "ceasing to promote Purdue opioid products to the particular HCP or providing further education to the HCP about appropriate use of opioids."

With respect to the first component, the Auditor's review of the materials maintained by the Law Department confirms that, when presented with an ADD Report, the Law Department (a) conducts inquiries and (b) those inquiries routinely include consideration of the HCP's prescribing history and other relevant facts about the HCP's practice. (See below discussion of the Law Department's determinations concerning ADD Reports at Section III.B.) Further, the Law Department Procedure requires such consideration. With respect to the second component of Paragraph 30.a., again based upon the Auditor's review of the materials provided by the Law Department, Purdue has in many instances ceased promoting Purdue products to HCPs as a result of its inquiries. (See below discussion of the Law Department's determinations of ADD Reports at Section III.B..)

Paragraph 30.b. of Section IV.A. requires that Purdue (a) immediately cease promoting opioid products to any HCP as to which an ADD Report has been filed, and (b) resume such promoting only after the Law Department "reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP." Both the ADD Procedure and the Law Department Procedure require such treatment of ADD Reports.

Specifically, the ADD Procedure provides that:

Once an ADD Report has been filed, notice will be provided that an internal inquiry is pending. While pending, no calls should be made on the Prescriber or Pharmacist that is the subject of the ADD Report until and unless a member of the Law Department provides written notification permitting such contact.

* * *

At the conclusion of the Law Department's internal inquiry, individuals with responsibility for calling on the Prescriber or Pharmacist will be informed, in writing, with a copy to appropriate

management, whether [sales representatives] may continue to promote Purdue opioid products to a particular Prescriber or Pharmacist who is the subject of the ADD Report.

The Law Department Procedure contains a similar requirement, stating in pertinent part that:

Law Department personnel will review the information gathered and prepare a memorandum that includes a recommendation concerning whether or not there is probable cause to believe that the HCP engaged in conduct described in the [ADD Procedure] and is someone to whom sales field personnel should cease promoting.

To ensure that these Procedures are followed, as described above Purdue has incorporated multiple alerts into the Phoenix system. Specifically, once an ADD Report is filed, the system generates an email by 6:00 a.m. the following morning. The Auditor has reviewed examples of such emails, which identify the name of the HCP in the subject line and body of the email, and state: “This HCP is under review by the Law Department. Calls should not be made on this HCP until notified by the Law Department.” The email also lists the names of the sales force employees who received the email.

Further, as explained above, if a sales representative seeks to schedule a call on a No-Call HCP, she will be confronted with a message highlighted in red stating that the HCP is a “NO CALL HCP.” The alert also states “Future calls should not be made on this HCP without approval from the Law Department” (emphasis in original). As discussed further below, sales representatives are trained not to call on HCPs when they receive these notifications via email or the Phoenix system.

Paragraph 30.c. of Section IV.A. requires that Purdue “implement and maintain a training program with respect to the ADD Program.” The training materials and related documents produced to the Auditor indicate that the Company is complying with this requirement. Based on those materials, Purdue requires the sales force to complete ADD training annually either in a live classroom setting or via WebEx and pass a quiz associated with the training. Although Purdue is only required under the AOD to train sales representatives and medical science liaisons on the revised ADD program, Purdue extended its training to include employees on managed health strategies and personnel from the Law, Compliance and Public Affairs departments as well. As of the end of July 2016, approximately 679 current Purdue employees had completed the training.

Purdue provided the Auditor with copies of both the ADD Training PowerPoint Presentation and the Quiz. The ADD Training presentation is titled “Field Force Risk Mitigation Programs” and covers both the ADD Procedure and Purdue’s policies with respect to their Order Monitoring System, which focuses on pharmacies. The presentation discusses among other things the types of employees who need to be aware of the ADD Program, the possible indicia of an ADD concern, and how to file an ADD report. The training also states that “No field based personnel should make further visits to the practice that is the subject of the report until and unless instructed otherwise by the Law Department” and discusses what happens during the Law Department review.

The training materials also direct the sales force to continue reviewing the status of HCPs in Phoenix to ensure the HCP is not on the No-Call List before making a call and state that the sales force must note ADD concerns in Call Notes. The materials further note that some

unexpected interactions with No-Call HCPs may occur and, if they do, must be documented in the Call Notes. The training materials also state that on the first call of each year beginning in January 2016, sales representatives in New York must ask whether the HCP completed the (REMS) training program regarding appropriate prescribing of opioids. If the HCP has not completed the training, the sales representative must provide the training materials to the HCP. Finally, the training materials discuss the incentive compensation implications and the possible disciplinary actions for failure to comply with the ADD Procedure, stating that the sales force may receive written warnings, probation, termination of employment, and may be ineligible for quarterly incentive compensation.

Paragraph 30.d. of Section IV.A requires that Purdue's sales incentive programs not provide any credits for sales of Purdue's opioid products once an HCP is placed on the No-Call List. The ADD Procedure, the Law Department Procedure and the ADD Training & Quiz all reflect this principle. For example, the ADD Procedure states that:

If the Law Department determines that a Prescriber or Pharmacist is a "no call," no sales incentive (bonus) shall be earned from prescriptions written by such Prescriber or Pharmacist for sales generated after such determination. Specifically, sales bonus will be calculated after the removal of the sales and sales history attributed to that Prescriber.

In practice, Purdue's quarterly incentive compensation process takes this principle into account as follows. When the Company calculates a sales representative's incentive compensation, it compares the actual sales made in that quarter to the representative's previously stated sales goal for the quarter. If an HCP in the sales representative's territory goes on the No-Call List during the quarter, two things happen. First, the value of any prescriptions written by that HCP are

omitted from the calculation of the representative's sales numbers. Second, the representative's sales goal for the quarter is also reduced. In reducing the latter, the Company informs us, the goal is to ensure that sales representatives may still reach their sales targets notwithstanding the absence of that HCP, and therefore are not discouraged from making ADD Reports.

Paragraph 31.a. of Section IV.A. contains two components. First, it requires sales representatives to check "whether HCPs they plan to call on that week are on Purdue's No Call list." Second, to the extent that a sales representative "promotes a Purdue opioid product on a planned call to an HCP on the No-Call List," such sales representative shall be subject to potential discipline.

With respect to the first component, Purdue's ADD Procedure requires that "each week, prior to making sales calls, all ADD Covered Persons shall create a call plan. Prior to making sales calls, ADD Covered Persons shall check whether the Prescribers or Pharmacists that they plan to call on that week have a 'no call' or 'under review' status in Phoenix." In practice, as discussed above it appears that sales representatives typically check Phoenix not just once a week, but multiple times each day, and the Phoenix system alerts sales representatives when an HCP they wish to detail is on the No-Call List.

With respect to the second component of Paragraph 31.a., while the Auditor is not in a position to assert with certainty that no sales representative has ever promoted an opioid product to an HCP on the No-Call List (only by monitoring the activities of all sales representatives in real-time could the Auditor make such an assertion), in our review of Call Notes we have not observed instances (except as discussed above at footnote 3, for example when the representative was so instructed by the Law Department) in which a sales representative made a planned call on

an HCP on the No-Call list. Because we have observed no instances of such intentional conduct, we are unable to evaluate whether it in fact has subjected a sales representative to disciplinary action.

Paragraph 31.b. of Section IV.A. requires that “Purdue may resume promoting Purdue opioid products to an HCP about whom an ADD Report has been filed only after its Law Department *in writing* reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP” (emphasis in original). Purdue’s policies and procedures are consistent with this requirement. For example, the ADD Procedure states that, while an ADD Report is pending, “no calls should be made on the Prescriber or Pharmacist that is the subject of the ADD Report until and unless a member of the Law Department provides written notification permitting such contact.”

In practice (as noted above), while the Auditor is not in a position to assert with certainty that no sales representative has ever intentionally detailed an HCP on the No-Call List, in our review of call reports we have not observed instances in which sales representatives intentionally and prematurely resumed promotion of opioids to an HCP prior to a determination by the Law Department. As discussed previously, the Company has informed us of 24 instances in which sales representatives had contact with No-Call HCPs. However, the materials provided by the Company indicate that none of these instances were intentional (except as directed by the Law Department so as to further its investigation of the HCP).

With respect to the requirement that the Law Department reach its conclusion that promotion may resume “in writing,” the Law Department Procedure requires that “Law Department personnel will review the information gathered and prepare a memorandum that

includes a recommendation concerning whether or not there is probable cause to believe that the HCP engaged in conduct described in the ADD Policy.” The Auditor initially asked to receive copies of these memoranda, but the Company asserted that they were covered by the attorney-client privilege. However, the Law Department described for us the facts contained in such memoranda, and upon our request also prepared written factual summaries that extracted and described those facts. Based upon the above, the Auditor believes that Purdue is complying with the “in writing” requirement.

Paragraph 31.c. of Section IV.A. requires that Purdue submit monthly reports to the OAG of the HCP names added to the No-Call List in New York. Purdue provided the Auditor with copies of the monthly reports the company has sent to the OAG, and based on this evidence it appears that Purdue is complying with this requirement.

Paragraph 31.d. of Section IV.A. requires Purdue to maintain other methods of identifying potential abuse “including but not limited to: (i) reviewing news media stories addressing the potential abuse, diversion, or inappropriate prescribing of opioids and/or the governmental investigation and/or arrest of HCPs to whom Purdue has promoted opioids; and (ii) examining data sources, such as HCP’s prescription history, to identify HCPs who should [be] reviewed for potential placement on the No-Call List.”

With respect to subparagraph (i), the Law Department Procedure is consistent with this requirement, stating that: “Purdue’s outside vendor for media services uses search terms to capture news stories concerning adverse criminal or licensing actions taken against HCPs nationwide (News Alerts). These News Alerts are emailed to the Law Department for review.” In practice, it appears this system has been successful since, according to the Law Department,

nationwide 314 HCPs were placed on the No Call List during the Auditor Review Period as a result of such alerts. With respect to subparagraph (ii), Purdue informed the Auditor that the company's Sales Operations department is analyzing sales data based on a review of certain factors and forwarding such analyses to the Law Department. While this has not yet resulted in the filing of any ADD Reports, Purdue is exploring the development of an internal program as well as engaging an external vendor to enhance this process and the Company's data analytics capabilities. As of the date of this Report, Purdue is still investigating options.

Paragraph 31.e. of Section IV.A. requires that performance evaluations of marketing employees "shall meaningfully take into account that sales persons inform HCPs . . . about [opioids'] potential for abuse and diversion, and how to minimize those risks." The Law Department Procedure is consistent with this requirement, stating:

On an annual basis generally expected to occur in 4th quarter, the Law Department shall ensure that sales force performance evaluations contain language regarding compliance with the ADD program so that such evaluations meaningfully take into account that such field personnel inform HCPs to whom they promote opioids about their potential for abuse and diversion, and how to minimize those risks.

Further, in Purdue's performance review forms, sales representatives and managers must acknowledge that such information was included. Specifically, the sales representative is required to acknowledge that "my performance evaluation will meaningfully take into account my compliance with policies and procedures including the expectation that I inform HCPs to whom I promote opioids about potential for abuse and diversion and how to minimize those risks." The manager is required to acknowledge that sales representatives' "evaluations will meaningfully take into account compliance with policies and procedures including the

expectation that sales personnel inform HCPs to whom they promote opioids about potential for abuse and diversion and how to minimize those risks.”

In addition to the above, the Company has informed us that it intends to implement a process for the next performance cycle to have any discipline of sales representatives provided to managers in advance of performance reviews being completed as a reminder that this issue needs to be addressed in the performance review. We will evaluate the Company’s progress with respect to this enhancement in our next report.

Paragraph 31.f. of Section IV.A. requires that if a sales representative fails to file an ADD report when she should have, that “person shall be subject to disciplinary action by Purdue, including but not limited to censure, probation and termination.” The ADD Procedure is consistent with this requirement, stating that:

Violations of this ADD Policy may result in disciplinary action including but not limited to written warning, probation, bonus ineligibility, or termination of employment. If the Law Department determines that an ADD Covered Person failed to file an ADD Report regarding a Prescriber or Pharmacist and the Company determines that individual knew or should have known that the Prescriber or Pharmacist was engaged in conduct covered by this ADD Policy, that will be considered a violation of this ADD Policy and will result in an ADD Covered Person being deemed ineligible for his or her quarterly bonus.

The ADD Training presentation is also consistent, and states in pertinent part that:

Violations of the ADD Policy may result in disciplinary action including, but not limited to:

- Written Warning
- Probation
- Termination of Employment
- Ineligibility for quarterly incentive compensation

Evaluation of whether the Company has complied with these procedures requires addressing two questions: (1) have sales representatives failed to file ADD reports when they should have?; and (2) in such instances, has Purdue subjected such representatives to disciplinary action? With respect to the first question, based on the nature of its review, the Auditor cannot answer with absolute certainty. To do so, the Auditor would need to review the Call Notes for every sales representative employed by Purdue, and it deemed such a review beyond the scope of this inquiry. However, the Auditor has reviewed extensive Call Notes and other materials during the course of its engagement, and with one exception noted below (see at 23) did not observe instances in which it concluded that the sales representative should have filed an ADD Report earlier than it should have.

With respect to the second question, because we have not observed instances in which a sales representative should have filed an ADD Report sooner, we cannot evaluate whether such a failure has subjected the sales representative to discipline. Purdue has informed us that as of September 15, 2016, there has been no discipline of a sales representative for failing to file an ADD report, and to date we have not observed evidence indicating that such discipline should have occurred. We will continue to monitor this in the next review period.

Paragraph 32 of Section IV.A. has two components. First, the paragraph requires that “ADD Covered Persons in New York shall enter detailed call notes regarding sales calls to HCPs in which compliance or potential abuse issues are raised.” Second, the Company’s Corporate Compliance department “shall, on a quarterly basis, audit and review a sample of such

call notes to, inter alia, evaluate compliance with the ADD Program and determine whether ADD Reports need to be filed regarding particular HCPs.”

With respect to the first component of paragraph 32, the ADD Procedure requires that

In the event that [a sales representative] learns of or observes any [ADD concerns] such activities or observations must be reported promptly in accordance with the procedures outlined below (“ADD Report”):

* * *

The ADD Report must be sent either through: (i) the Call Note functionality in Phoenix or (ii) by email to Drug Safety and Pharmacovigilance (“DSP”) using the ADD Form.

The ADD Training presentation is similar in content.

In practice, without monitoring in real time the activities of all Purdue sales representatives, the Auditor cannot determine with absolute certainty whether all sales representatives are complying with this requirement. However, as discussed further below, the Auditor has reviewed the Call Notes for many sales representatives in which they appropriately raised concerns about potential abuse.

With respect to the second component of paragraph 32, the ADD Procedure requires that:

The Corporate Compliance Department shall audit and review call notes to evaluate compliance with this ADD Policy. Should Compliance determine that an ADD Report may have been required, the call notes will be referred to the Law Department for further review.

In addition to the ADD Procedure, the Company has also issued an Ethics & Compliance Call Note Review-Working Practice Document (the “Compliance Review Procedure”), which describes the procedure for this review. The Compliance Review Procedure states that on a

weekly basis the Phoenix system will forward Call Notes containing certain search terms, as well as randomly selected called notes, to the Ethics and Compliance Department for review.⁴ If the reviewer finds a Call Note that raises ADD concerns and no ADD report was filed, the issue is forwarded to the Law Department for further action.

During the Auditor Review Period, the Ethics and Compliance Department brought three Call Notes to the attention of the Law Department. The first call note was determined not to relate to the ADD Program because it mentioned that an HCP's nephew had an addiction problem, which might cause the HCP not to want to prescribe Hysingla. The second call note also was determined not to relate to the ADD program because it mentioned a Board of Pharmacy visit concerning a product (ZoHydro) generally considered to be abuse deterrent. The third email, however, did involve the potential abuse of OxyContin, and should have led to filing of an ADD Report. The Law Department has informed us that it conducted follow-up with the sales representative, who indicated that she was aware of her ADD requirements, and had flagged the incident as an adverse event in her Call Notes. In response, the Law Department reinforced the need to report potential abuse and diversion in an ADD Report and not just a call note, as well as provided additional coaching. In light of the above facts, the Law Department concluded that disciplinary actions was unwarranted.

⁴ In response to a suggestion by the Auditor, on August 26, 2016, Purdue updated the Compliance Review Procedure to specifically state that the compliance reviewer must review the call notes for the situations specified in Purdue's ADD Procedure and added a reference to the ADD Procedure. Purdue also updated its Law Department Procedure as of September 1, 2016, to refer to the new version of the Compliance Review Procedure.

Paragraph 33 of Section IV.A. requires that, in Purdue's compensation structure for marketing employees, no more than 30% of an individual's total compensation (including bonus) may be based on the volume of OxyContin prescriptions. Based on information provided by the Company, Purdue's sales force receives base salary and incentive compensation (bonus) payouts. Incentive compensation is broken down by OxyContin, Butrans and Hysingla ER. If a sales representative's focus is Butrans, a significant percentage of that person's bonus will be based on sales of Butrans. If a sales representative's focus is Hysingla ER, a significant percentage of that person's bonus will be based on sales of Hysingla ER.

Purdue's Incentive Compensation Guides for the sales force, including managers, for the first two quarters of 2016 state that their OxyContin Retail Incentive is 20% of their target incentive compensation. Accordingly, a sales representative's bonus can never be more than 20% based on sales of OxyContin. This percentage does not take into account the total compensation which would include the base salary.

To monitor compliance, prior to any incentive compensation payments, the Law Department, Sales Operations Department and Human Resources Department monitor these payments and review the percentage of OxyContin payout compared to total compensation to monitor compliance. (See Law Department Procedure, stating "The Law Department, Sale Operations and Human Resources will monitor incentive compensation payouts to the sales force on a periodic basis throughout the year to ensure that no more than 30% of that individual's total compensation (including bonus) will be based on the volume of OxyContin prescriptions.")

B. Purdue's Decisions Regarding Whether to Continue Marketing During the Auditor Review Period

Pursuant to Paragraph 41.b. of the AOD, the Auditor obtained from Purdue each of the ADD Reports filed and closed during the period from January 1 through June 22, 2016. As noted above, during the Auditor Review Period, 98 new ADD Reports were submitted and closed. Of these 98 ADD Reports, the Law Department initially determined to cease calling 73 HCPs, and to continue calling 25 HCPs. Following discussions with the Auditor and further consideration, the Company changed its classification with respect to 5 of those HCPs, and either placed them on the No-Call List or is subjecting them to further review. Thus, in the final analysis, the Company determined to cease calling 76 HCPs, determined to continue calling 20 HCPs, and has two HCPs still “under review,” which effectively means that the HCPs go back on the No-Call List while the Law Department continues its investigation.⁵

1. Parameters Governing the Auditor's Review

As required by the AOD, the Auditor has evaluated the reasonableness of the Company's determinations. In doing so, the Auditor adopted and applied the following guidelines. First, the Auditor sought to determine whether the Company's decision was reasonable, and not whether the Auditor agreed or disagreed with that decision. In certain instances (discussed below), reasonable minds could differ as to whether continued promotion to a particular HCP was appropriate. However, under the AOD the Auditor's role (to our understanding) is not to supplant the Auditor's judgment for that of the Company, but rather to determine whether the Company's judgment was reasonable under all the circumstances.

⁵ The Company also changed the determination for two Requests to Resume Calling from continue calling to cease calling.

Second, the Auditor used the following definition of the term “appropriate.” Under paragraph 31.b. of the AOD, the Company may resume promoting to an HCP on the No-Call List only after the Law Department reasonably concludes, based on available information, that such resumption is “*appropriate*” (emphasis added). The AOD, however, does not define that term, and accordingly the Auditor developed its own definition, based on its understanding of the AOD’s purpose. In doing so, the Auditor considered two factors: first, the level of risk (for example, should the Company place an HCP on the No-Call list if there was *any* risk, no matter how small, of the HCP engaging in illegal conduct -- effectively a zero tolerance approach -- or only if there was a significant risk of such conduct); and second, the nature of the risk (for example, should the Company place an HCP on the No-Call list if there was evidence that the HCP himself had a personal substance abuse issue, or only if the evidence suggested a risk that the HCP might engage in improper and illegal prescribing of opioids for the purposes of diversion to patients). Taking into consideration these parameters, the Auditor applied the following definition of the term “appropriate:” resumption of marketing to an HCP on the No-Call List is appropriate only if such resumption does not present a significant risk that the HCP would engage in illegal abuse and diversion of opioids.⁶

Third, the Auditor focused most of its attention on those cases in which the Company made the determination to continue calling, as opposed to those cases in which it made the determination to cease calling. While the latter are clearly relevant and instructive, we believe that the continue calling determinations presented a higher degree of risk and merited a higher

⁶ Of course, if this definition differs from the Attorney General’s, we would be happy to discuss an alternate approach.

level of attention. Thus, the Auditor focused in particular on those instances where the Company made the determination to continue calling on an HCP.

Fourth, the Auditor also reviewed the Company's determinations on Requests to Resume calling, even if the HCP had been placed on the No-Call List in previous years. As we understand it, the AOD does not require such review, since Paragraph 41 of the AOD only requires the Company to provide the Auditor with ADD Reports filed during the review period, and in these instances the ADD Reports were filed in earlier periods. Nevertheless, in a spirit of full disclosure the Company volunteered to provide us with these determinations, and thus we have also taken them into account.⁷

Based on the above guidelines, set forth below is the Auditor's evaluation of selected determinations made by the Company during the Review Period. Due to space limitations the Report does not discuss each and every determination made by the Company, but instead discusses those which we believe to be representative. Broadly speaking, our evaluations of those determinations fall into three categories: (a) instances in which the Auditor found the Company's determination to continue calling reasonable; (b) instances in which the Company initially determined to continue calling, and then after discussion with the Auditor and further reconsideration determined to cease calling; and (c) instances in which the Auditor found the Company's determination to continue calling reasonable, but which were closer calls and raised issues of possibly broader application that the Auditor wished to bring to the OAG's attention. Each of these categories is discussed below in turn.

⁷ During the Auditor Review Period, the Law Department reviewed 15 Requests to Resume calling on an HCP who had been placed on the No-Call List due to an ADD Report filed in an earlier year.

2. Continued-Calling Determinations Found Reasonable

Selected examples of the Company's determinations to continue calling, and how the Company arrived at them, are described below.

Dr. Shannon Finch. On or about January 19, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. Shannon Finch, a primary care physician located in Bristol, Virginia. The report was based upon a comment made to the representative by a local pharmacist, who reported a concern with some of the prescriptions coming out of Dr. Finch's office. Specifically, the pharmacist said he had seen multiple instances in which two separate short-acting therapies (for example, 180 hydrocodone and 300 oxycodone) had been prescribed for the same patient.

In response to the Report, the Law Department spoke with three different sales representatives, the one who had previously covered Dr. Finch (and filed the ADD Report), and the two sales representatives who were currently calling on the doctor. All gave positive reports, with one indicating that she was "very surprised" to learn of the Report, and stating among other things that she had called on Dr. Finch for many years and never observed anything that suggested improper conduct. Moreover, during her conversations with Dr. Finch, the doctor had shown awareness of the recommendations for prescribing pain medications and recognized the benefits of extended release products with abuse deterrent properties. She did recall one incident in which a pharmacist had questioned one of Dr. Finch's prescriptions, but that was because Dr. Finch was a primary care physician and the pharmacist thought the patient needed a pain management doctor.

In addition to contacting the three sales representatives, the Law Department reviewed the Call Notes, Dr. Finch's medical license (which was active), her DEA registration (active), her prescribing history (which showed a consistent rate of prescriptions for combination opioids such as a generic consisting of acetaminophen and hydrocodone, but very limited prescriptions for OxyContin) and located no publicly available negative information. The Law Department also took into account their experience with the ADD Program over the years, which indicated that certain pharmacists could be particularly sensitive when filling prescriptions for opioids. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Fitch.

Dr. Rita Harrison. On or about February 4, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. Rita Harrison, a practitioner located in Gettysburg, Pennsylvania. The report was based upon interactions the sales representative had with the doctor's husband, who apparently had begun to take a role in the practice, and had posed a number of questions to the sales representative about Purdue products. The husband also mentioned that Dr. Harrison had been treating him for addiction, and mentioned that local pharmacies had declined her prescriptions.

In response, the Law Department spoke to the sales representative, who reported that in her 18 months of calling on Dr. Harrison she had found the doctor both legitimate and professional. The concern that had led her to file the ADD Report was not with Dr. Harrison, but rather with the doctor's husband and whether he might have an undue influence on the practice. The Law Department directed the sales representative to revisit the office at a later date along with her manager, in an effort to determine whether the nature of the practice had changed.

After that follow up visit in April, the sales representative reported that she and her manager had spoken to Dr. Harrison, and had observed nothing of concern during their visit to the offices.

In addition to the above, the Law Department reviewed the Call Notes, Dr. Harrison's medical license (active), her DEA registration (active), her prescribing history (which showed a consistent rate of prescriptions for suboxone, used for treatment of addiction, but small numbers of prescriptions for single entity and combination opioids) and located no publicly available negative information. Based on the above, the Law Department determined that it was appropriate to continue calling on Dr. Harrison.

Dr. Nathan Perrizo. On or about February 9, 2016, a sales representative submitted an ADD Report concerning Dr. Nathan Perrizo, a pain specialist located in Encinitas, California. The ADD Report stated that Dr. Perrizo had reported to the sales representative that one of his prescription pads had been stolen, as a result of which approximately 10% of his previous oxycodone prescriptions had been forged. In response, the Law Department interviewed the sales representative, who reported among other things that: (i) she had been calling on Dr. Perrizo for over three years; (ii) in her view he was a conservative, careful prescriber as to whom she had "absolutely no concerns;" and (iii) his office takes extra measures to ensure they are prescribing within guidelines, and had implemented procedures to protect against future thefts.

The Law Department also reviewed the Call Notes, Dr. Perrizo's medical license (active), his DEA registration (active), his prescribing history (which showed few prescriptions for OxyContin and Oxycodone, and consistent levels of prescriptions for generic combination opioids such as Norco) and located no publicly available negative information. Based on the

above facts, the Law Department determined that it was appropriate to continue calling on Dr. Harrison.

**3. *Initial Determinations to Continue Calling
Revisited and Changed Following Input from the Auditor***

As noted above, in some instances the Company initially made a determination to continue calling, and subsequently changed that determination after discussion with the Auditor and further consideration. Purdue changed three determinations from continue calling to cease calling and two determinations from continue calling to under review, which, as mentioned above, effectively means that the HCPs will go back on the No-Call List while the Law Department continues its investigation. Examples of those determinations, and how the Company arrived at them, are described below.

Dr. William Wilson. On or about February 4, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. William Wilson, an osteopath located in Pensacola, Florida. The report was based upon an interaction the sales representative had with the doctor, in which he was speaking slowly and with slurred speech. While the sales representative later clarified that she had been concerned about the doctor's health, and not potential substance abuse, in researching the doctor's background the Law Department learned other significant information. Specifically, the doctor's registration records indicated that, while his Florida license was active, Dr. Wilson was under "obligations" to the state medical board based upon complaints made against him in earlier years that he had prescribed controlled substances to two patients in an excessive and inappropriate way. As a result, the doctor had agreed to completing courses in

prescribing controlled substances and maintaining adequate records, as well as to having a risk manager review his practice and procedures.

The Law Department initially determined that it was appropriate to continue calling on Dr. Wilson for a number of reasons, including that his medical license and DEA registration were active, the complaints against him were in the past and he had apparently worked successfully with the risk manager overseeing his practice. Also, his prescribing history showed a consistent pattern, and in fact his prescribing of opioids (predominantly combination opioids such as Norco generic or Percocet) had steadily declined. The Auditor agreed that these considerations were reasonable, but felt that, given the nature of the complaints made against Dr. Wilson (the excessive prescribing of opioids to two patients), it would be more prudent to cease calling, and the Company agreed.

Dr. Tam Nguyen. On or about March 7, 2016, a Purdue sales representative submitted a request to resume calling on Dr. Tam Nguyen, an osteopath located in San Jose, California. Dr. Nguyen had been on the No-Call list since 2012, following a sales force report that he was under investigation by the DEA. In researching the request, the Law Department learned that in 2013 Dr. Nguyen had entered into a stipulated settlement with the California Medical Board, based on an allegation that he had written improper and excessive prescriptions to several patients without conducting adequate examinations or keeping adequate records.

The Law Department initially determined that it was appropriate to remove Dr. Nguyen from the No-Call List for a number of reasons. Among them were that, although placed on probation, his medical license and DEA registration were valid. Further, his prescribing history showed little use of single entity opioids, and consistent and moderate levels of combination

opioids. The Auditor agreed that these considerations were reasonable, but nevertheless believed that, given the nature of the complaints made against Dr. Nguyen, it would be more reasonable not to resume calling, and the Company agreed.

Dr. Richard Brown. On or about February 9, 2016, a sales representative submitted an ADD Report concerning Dr. Richard Brown, a physician with a pain practice in Detroit Michigan. The sales representative stated that Dr. Brown's office had mentioned it was visited by the DEA and that Dr. Brown did not do urine screen tests. In discussions with the Law Department, the representative also mentioned that Dr. Brown's opioid prescriptions had dropped significantly, and she believed that the drop was related to the DEA's visit. The prescribing history confirmed that the doctor had written a consistently high level of prescriptions in the months prior to October 2015, then showed a dramatic drop in November 2015, only to resume to a higher level again in January.

In order to evaluate Dr. Brown's practice more fully after receiving the ADD Report, the Law Department asked the sales representative to visit Dr. Brown again. The representative learned that Dr. Brown was now doing urine testing and mapping on all patients taking pain medication. Accordingly, the representative advised the Law Department that she felt Dr. Brown had put appropriate measures in place and did not have any ADD concerns about him. Based on the above facts, and taking into consideration the doctor's medical license (active), DEA registration (active), and absence of any negative public information, the Law Department determined that it was appropriate to continue calling on Dr. Brown. The Auditor agreed that these considerations were reasonable, but given the fact of the DEA visit and the dramatic drop and then increase in Dr. Brown's prescriptions, which appeared to be related to the visit, believed

it would be more prudent to cease calling. The Company has agreed to further investigate Dr. Brown and, accordingly, placed him under review.

4. *Determinations Found Reasonable, but Raising Issues for the OAG's Consideration.*

As noted above, in several instances the Auditor found the Company's determination to continue calling reasonable, but the determination raised issues of more general application that the Auditor wished to bring to the OAG's attention. Certain of these instances are discussed below.

Personal Substance Abuse Issue. In a number of instances, the issue that placed a doctor on the No-Call List was a personal struggle with substance abuse. For example, Minnesota anesthesiologist Dr. Annie Burton was the subject of an ADD report submitted by a sales representative on or about March 16, 2016. The sales representative reported that she had heard that Dr. Burton's license might be restricted, and the Law Department's research determined that in 2008 and again in 2014 Dr. Burton had herself had an issue with opioid dependence. She self-reported the 2014 problem to the medical board, and in 2015 her license was suspended, but the suspension was waived so long as she complied with certain conditions. Specifically, she was required to practice in a group setting approved by the medical board, she must have no access to controlled substances, and she could not prescribe for herself or her family.

In response to the above concerns, the Law Department spoke to the sales representative to obtain information on the conditions under which Dr. Burton was practicing. The Department learned that Dr. Burton in fact was working under the direction of the medical director of her practice, and that the practice as a whole raised no ADD concerns. The Law Department also

reviewed Dr. Burton's prescribing history, which showed a *de minimis* amount of prescriptions. Based on these facts, as well as Dr. Burton's DEA registration (active), and the absence of any negative publicly available information, the Law Department concluded that it was appropriate to continue calling on Dr. Burton.

The Auditor concludes that this determination was reasonable. However, because personal substance abuse is specifically listed as a "red flag" in paragraph 10 of the AOD, and because the issue has appeared in other ADD Reports, the Auditor believed it should identify the issue for the OAG. In the Auditor's view, while a personal substance abuse issue is certainly a red flag that merits careful attention, it does not represent a disqualifying factor where the issue can be controlled and the HCP does not present a significant risk of illegal overprescribing to others. In the Auditor's view, this represents such a case.

Request for Patient Records by DEA. In several instances, the issue that placed an HCP on the No-Call List was information indicating that the DEA had requested records, not for the HCP, but for the patients of a practice. For example, four HCPs -- Dr. Chloe Dent, Physician's Assistant Christopher Kreider, Physician's Assistant Rita Kurinets and Nurse Practitioner Bonnie Wilenksy -- all worked for the same group pain practice in Boulder, Colorado. In or about January 2016, a sales representative submitted an ADD Report stating that she had recently learned that the DEA had requested records for 13 of the practice's current patients.

In response, the Law Department interviewed the two sales representatives who called on the practice, as well as their District Manager. One of the sales representatives had called on the practice approximately once a week for over 2 years, and observed that, while the practice treated a number of patients with complicated medical issues for whom other medical options

had been exhausted, she had never observed anything giving rise to ADD concerns. To the contrary, she reported that the practice routinely does urine drug screens and enters into patient contracts governing their use of pain medications. The providers were also involved in educational events, and sought to lower doses of opioids where possible. The prescription history for the doctor in the group (Chloe Dent) was not excessive, and showed consistency over time. Based on the above factors, the Law Department concluded that continuing to call on these HCPs was appropriate.

The Auditor found the Law Department's determination reasonable. However, because the ADD Report suggested the possibility of a DEA investigation (albeit one focused on the patients), and any such law enforcement investigation raises obvious concerns, the Auditor believed that this case should be brought to the OAG's attention. Many if not most of these cases present judgment calls where the ultimate question is whether the practice at issue is a responsible one sensitive to the risks of abuse, or an irresponsible one that embodies exactly such risks. Here, based on the above due diligence the Auditor is comfortable with the Law Department's conclusion that this practice represents the former rather than the latter.

Doctor on Probation but Subject to Supervision of Monitor. In some instances, the issue that placed a doctor on the No-Call List was information indicating that the doctor was on probation, but subject to the supervision of a monitor to address the issues that had caused the probation. For example, Dr. Daniel Mazour had a pain management practice in Franklin, Nebraska. On or about February 1, 2016 a sales representative submitted an ADD Report stating that Dr. Mazour had been the subject of disciplinary action by the Nebraska Department of Health and Human Services. In researching the allegation, the Law Department determined that

Dr. Mazour's license was in fact on probation until January 2020. According to a local news article, the probation resulted from insufficient consultation with patients, lack of documentation and unprofessional standards of conduct in prescribing controlled substances.

In response, the Law Department sought more information concerning the terms of Dr. Mazour's probation. The Law Department learned that Dr. Mazour would be supervised by a licensed monitor, and could not prescribe until that monitor was in place. He was also required to take courses on record keeping and prescribing narcotics, and his DEA registration was current. Finally, interviews with the sales representative indicated that he had not observed red flags at Dr. Mazour's practice and that, after he advised the doctor concerning cautionary steps such as drug testing and firing of non-compliant patients, the doctor began to implement such procedures. For all those reasons, the Law Department determined it was appropriate to continue calling on Dr. Mazour.

The Auditor concludes that the Law Department's determination was reasonable. However, any time an HCP is on probation for issues that touch upon the prescribing of controlled substances, such probation raises obvious issues that go to the heart of the AOD, and therefore the Auditor wished to bring this case to the OAG's attention. Under the AOD, a credible allegation that an HCP is under investigation by a regulatory authority is of course a red flag, and here the doctor was on probation for related conduct. On the other hand, while such probation is clearly a red flag that merits careful attention, it does not in the Auditor's view represent a disqualifying factor so long as the issues are addressed and controlled. Here, based on the above facts, and particularly given the role of the monitor overseeing Dr. Mazour's practice, the Auditor concluded that the Law Department's judgment call was a reasonable one.

IV. Additional Questions Posed by the OAG

In September 2016, the OAG raised four additional questions for the Auditor's consideration, and asked that the Auditor address them in the Report. Set forth below are the OAG's questions and the Auditor's findings.

A. Explanation for Absence of Sales Force ADD Reports in New York

As noted above, and as the OAG is aware, during the Auditor Review Period no ADD Reports were filed in New York based on sales force field observations. The OAG has asked whether the Auditor can determine an explanation for the absence of sales force reports in New York. In brief, the Auditor can offer speculation as to that subject, but not a definitive answer.

A possible explanation is that the decline in sales force ADD Reports results from a corresponding decline in the numbers of sales representatives, HCPs detailed and sales visits. We have requested this information from Purdue, which reports that from 2015 to 2016: the average number of sales representatives in New York dropped from approximately 40 to approximately 30; the number of HCPs targeted for calls dropped from approximately 3,000 to approximately 1,700; and during the Audit Review Period only approximately 1,100 of these HCPs were actually called upon.

Further, based on information provided by the Company, there has been a downward trend in ADD Reports based on sales force observations over the past 5 years, as reflected by the below chart:

<u>Year</u>	<u>ADD Reports Based on Sales Force Observations</u>
2011	7
2012	10
2013	9
2014	3
2015	2

Given the above statistics, and the fact that 2016 is not yet completed, the decline in sales representatives and sales calls is a plausible explanation for the decline in sales force ADD Reports, but of course this amounts to no more than speculation.

What is not speculation, however, is that many sales force ADD Reports have been filed in other parts of the country. Many of the ADD Reports reviewed by the Auditor for purposes of this Report arose from sales force observations, in states as different as Florida, Nebraska, Pennsylvania, Michigan and California. In the course of its review the Auditor has seen no evidence that Purdue is treating the State of New York differently, in a way that would lead to fewer ADD Reports from the field. In any event, the Auditor will continue to monitor this in the next review period.

B. Review of Call Notes for Steven Parry

The OAG has observed that Dr. Steven Parry was placed on the No-Call List in or about February 2016, but only as a result of his indictment in a criminal case. Because Purdue detailed Dr. Parry during the years between 2004 and 2015, the OAG has asked whether Purdue failed to act on red flags that should have led to an earlier placement on the No-Call List. The Auditor has seen no evidence of such overlooked red flags.

The Auditor has reviewed the Call Notes for Dr. Parry, and has observed no indication

that the sales representatives should have noticed that Dr. Parry was overprescribing. In addition to the Call Notes, the Auditor has reviewed Dr. Parry's prescribing history. Based upon the history received from the Company, during the period between June 2014 and May 2015, Dr. Parry wrote between approximately 160 and 220 opioid prescriptions per month, amounts smaller than the Auditor has observed for many other doctors. Very few of these prescriptions were for single entity opioids, and most were for combination opioids such as Norco generic. Fewer still were for Purdue products, with Dr. Parry prescribing in the range of 10 per month. Based on the Auditor's review of the prescribing histories for other doctors, Dr. Parry's would not stand out as a red flag.

C. Review of Call Notes for Other HCPs

Based on the example of Dr. Parry described above, the OAG has focused the Auditor's attention on other HCPs placed on the No-Call List for criminal conduct during 2016, and asked whether Purdue missed red flags with respect to them. As discussed below, the Auditor concludes that it did not.

In 2016, based on information obtained from the Law Department, Purdue placed 22 NY HCPs on the No-Call List due to the filing of criminal charges or medical licensing issues. Of those 22, Purdue did not call on 19 of them. Of the remaining three, only two faced criminal charges: one was Dr. Parry and the other was Dr. Peter Lesniewski.

Dr. Lesniewski was placed on the No-Call List after a February 2, 2016 article stated that he was convicted in 2014 for his role in a scheme to provide fraudulent disability applications for Long Island Railroad workers. While the criminal charges did not involve opioid prescribing, the Auditor nevertheless reviewed Dr. Lesniewski's Call Notes and they contain no indication of

overprescribing. Because he was placed on the No-Call List as a result of a media report, the Company did not have a prescribing history for Dr. Lesniewski, so the Auditor was unable to review that. Based on the available information, however, the Auditor does not conclude that the Company overlooked a red flag with respect to this doctor.

D. Process Error with Respect to Dr. John Sciales

The OAG has focused the Auditor's attention on a processing error that resulted in sales calls being made on Dr. John Sciales after he was placed on the No-Call List. We have discussed this issue with the Law Department, which reports that the issue arose from two sources. First, a coding error was made when entering the No-Call determination for Dr. Sciales into the Phoenix system. Second, the error was overlooked by the prior attorney handling the ADD Reports. The Law Department advised that several steps have been taken to address the issue: assigning different employees to the coding process; reducing the number of code options in the database to avoid coding errors; and Law Department review of all such coding work on a contemporaneous basis. The Auditor will monitor these improvements going forward.

V. Prospective Plan of Action

In the upcoming review period, the Auditor plans to continue evaluating Purdue's Compliance with AOD Section IV.A. In particular, the Auditor will periodically confirm with Purdue that all new staff receive the ADD Training & Quiz. The Auditor will also follow-up on Purdue's compliance with AOD Section IV.A.31.d.ii. to determine whether Purdue has begun to utilize an outside vendor to examine data sources such as an HCP's prescription histories as part of its ADD Program. The Auditor plans to also specifically monitor certain activities in New York, and has suggested conducting interviews of members of the New York sales force to

measure awareness of their ADD obligations.

In addition to the above, the Auditor will of course continue to evaluate Purdue's determinations regarding ADD Reports. Rather than wait until the end of the review period to do so, the Auditor and the Law Department have discussed doing that on a quarterly basis. To enhance that review and evaluation, the Auditor recommends certain process improvements. As discussed above, in order to facilitate the Auditor's work in the current Review Period, the Law Department prepared summaries of the facts relevant to its determination. Going forward, the Auditor recommends that the Law Department: (1) prepare the factual summaries contemporaneously with its determinations; (2) ensure that the factual summaries reflect all of the facts relevant to the Law Department's determinations; and (3) institute a check off system with respect to the factual summaries, which would reflect that both of the attorneys involved in the review process have initialed the fact summaries to indicate their approval. These enhancements will strengthen both the Law Department's determination process and the Auditor's evaluation of the results.